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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,883	12/15/2003	Diane Lipscombe	B0877.70026US00	6781
23628 7590 01/30/2007 WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER STANDLEY, STEVEN H	
			ART UNIT	PAPER NUMBER
			1649	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/30/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/736,883	<b>Applicant(s)</b> LIPSCOMBE ET AL.	
	<b>Examiner</b> Steven H. Standley	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 37-44 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,39,40,43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 37-38, 41-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group II and human as a species in the reply filed on 11/09/06 is acknowledged.

Claims 1-2, 37-38, 41, and 42 are under examination.

### ***Priority***

Priority is to the provisional application, 60/443474, filed Jan. 29, 2003.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Note that 37 CFR 1.98.

### ***Claim Objections***

Claim 1-2 are objected to because of the following informalities: The claims include the use of brackets to indicate the inclusion of exon 37a as e[37a]. However, the inclusion of brackets in a claim indicates that the enclosed subject matter is to be deleted. See MPEP section 2234 paragraphs (2), and (f). Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 37-38, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al (Society for Neuroscience Abstract, November 2001).

Pan et al disclose the splice variant exon 37a in a human N-type calcium channel. Pan et al further disclose expression of human CaV2.2 splice variants in *Xenopus* Oocytes for analysis of the functional characteristics of CaV2.2 splice variants. Pan et al disclose at the end of the abstract, "Future analyses will establish the expression patterns of exon pairs, 37a/37b...of CaV2.2 alpha1 subunit, and their effects

Art Unit: 1649

on N-type Ca channel function.” Thus, one of ordinary skill in the art would have been motivated to test the human splice variant CaV2.2e37a in a *Xenopus* Oocytes to determine the functional effect of the splice variation, and further in neurons, because that is where they are normally expressed (as disclosed in the instant Abstract). There would be quite a high expectation of success, since expressing recombinant proteins in heterologous cells such as *Xenopus* Oocytes, and in neurons, is strictly a matter of routine experimentation in the art.

**37 CFR 1.105**

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

In response to this requirement, please provide copies of each publication which any of the applicants authored or co-authored and which describe the disclosed subject matter of the reference by Pan et al (cited above under 35 USC § 103) as well as reference Bell et al (Society for Neuroscience Abstract, 2001) with the same senior author (Lipscombe). These are both abstracts submitted for the Society for Neuroscience (SFN) meeting in November of 2001, a scientific meeting. Presentations at scientific meetings often disclose to the public considerably more than what is written in the abstract. For example, presentations can include a poster or slides, each depicting the same subject matter submitted in abstract form in considerably greater detail. For instance, either one of the abstracts at this meeting could have disclosed the

Art Unit: 1649

sequence of the splice cassette exon 37a, and recombinant expression of that human CaV2.2e37a splice variant in either *Xenopus* Oocytes or neurons.

Applicant is required, in response to this requirement, to provide copies of any poster, slides, or similar such material that may have actually been presented to skilled artisans at the SFN meeting for which the Pan et al. and Bell et al. references are abstracts. The first listed inventor is the senior author on both Abstracts. If no oral, slide, or poster presentation was made at the scientific meeting, and the written abstracts by Pan et al and Bell et al in fact constitute the entirety of the public disclosure at the SFN meeting, applicant should explicitly confirm this.

This requirement is deemed necessary for the examiner to determine the patentability of the invention now claimed. Pan et al. disclose the identical products as recited in the claims, and may further teach the sequence of e37a in human CaV2.2 recombinantly expressed in cells. Bell teaches analysis of CaV2.2 splice variants in neurons as well, and may disclose human CaV2.2e37a recombinantly expressed in neurons or *Xenopus* Oocytes.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement

Art Unit: 1649

under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.

1/17/07



JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER